AUBREY INC.
5390 Sea Lion Place, Suite 100
Carlsbad, California 92010
(760) 602-8303 P
(760) 602-8304 F

510(k) SUMMARY

FEB - 6 2009

Submitted by:

Stephen W. Moss
President
AUBREY INC.
5930 Sea Lion Place, Suite 100
Carlsbad, California 92009
(760) 602-8303 Phone
(760) 602-8304 Fax

September 23, 2008

Device
Name: *AW*BAT
Trade Names: *AW*BAT-*S*, *AW*BAT-*D*, *AW*BAT-*M*
Common Name: Wound Dressing, Collagen
Classification Name: Unclassified
Product Code: KGN

Predicate Device
Name: Biobrane®
Trade Names: Biobrane®, Biobrane®-L
Common Name: Wound Dressing, Collagen
Classification Name: Unclassified
Product Code: KGN

Description of Device

A Temporary Wound Dressing for coverage of Superficial burns, Donor sites and Meshed autografts until healing occurs. *AW*BAT is composed of a single or multiple filament knitted nylon fabric, bonded to a thin porous silicone membrane (approx 0.001 inch). The nylon side of these components is coated with a non-toxic mixture of porcine collagen peptides.

*AW*BAT is manufactured in 12"x12" sheets that are cut to sizes of 3"x3", 6"x6", 6"x12" and 12"x12" and ink stamped "*AW*BAT-*S*," "*AW*BAT-*D*" or "*AW*BAT-*M*" accordingly.

*AW*BAT-*S* has pores in the silicone membrane at 1/4" centers and the approximate area of an *AW*BAT-*S* pore is 0.0036 square inch each.

*AW*BAT-*D* has pores in the silicone membrane at 1/4" centers and the approximate area of an *AW*BAT-*D* pore is 0.0073 square inch each.

*AW*BAT-*M* has pores in the silicone membrane at 1/4" centers and the approximate area of an *AW*BAT-*M* pore is 0.0070 square inch each.

The following table addresses the Design and Use of the Device:

Question	Yes	No
Is the intended device for prescription use?	Yes*	
Is the intended device for over-the-counter use?		No
Does the device contain components derived from a tissue or other biological source?	Yes**	
Is the device provided sterile?	Yes	
Is the device intended for single use?	Yes	
Is the device a reprocessed single use device?		No
If yes, does this device type require reprocessed validation data?		N/A
Does the device contain a drug?		No
Does the device contain a biologic?	Yes**	
Does the device use software?		No
Does the submission include clinical information?		No
Is the device implanted?		No

**AW*BAT is intended for application by a physician.
***AW*BAT contains a xenogenic component: porcine type 1 collagen (gelatin).

*AW*BAT-*S* is composed of a 15/2 denier multiple filament nylon knitted fabric, bonded to a thin porous silicone membrane. The nylon side of these components is coated with a non-toxic mixture of porcine collagen peptides (xenogenic component).

*AW*BAT-*D* has the same composition as *AW*BAT-*S*, except it is more porous to enable the clinician to evacuate a clot through the membrane into an outer sterile wrap.

*AW*BAT-*M* has the same composition as *AW*BAT-*D*, except the 12/1 denier nylon fabric is monofilament (thinner & less adherent).

Intended Use of the Device

Temporary wound dressing for coverage of Superficial burns, Donor sites and Meshed autographs.

*AW*BAT-*S*: is intended for clean Superficial burn wounds.

*AW*BAT-*D*: is intended for Donor sites after hemostasis has been established.

*AW*BAT-*M*: is intended to be used as a protective covering for Meshed autografts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Aubrey Inc.
% E. Aurbrey Woodproof, PhD, MBA
Chairman and CEO
5390 Sea Lion Place, Suite 100
Carlsbad, California 92010

FEB - 6 2009

Re: K082869
Trade/Device Name: AWBAT™ (AWBAT-*S*, AWBAT-*M* and AWBAT-*D*)
Regulatory Class: Unclassified
Product Code: KGN
Dated: January 30, 2009
Received: February 2, 2008

Dear Dr. Woodproof:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K082869

Device Name: *AW*BAT™ (*AW*BAT-*S*, *AW*BAT-*M* and *AW*BAT-*D*)

Indications for Use: AWBAT-S is intended for clean Superfical burn wounds.

AWBAT-D is intended for Donor sites after hemostasis has been established.

AWBAT-M is to be used as protective covering for Meshed autografts.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082869